



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a virtual meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held December 4, 2020. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: <http://www.hhs.gov/nvpo/nvac/meetings/index.html> at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting or participate in public comment. Please register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, at the Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Mary E. Switzer Building, Room L618, 330 C Street SW, Washington, DC 20024. E-mail: nvac@hhs.gov. Phone: 202-695-9742.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program’s responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During this NVAC meeting, NVAC will hear presentations to support the recent charge from Admiral Brett P. Giroir, MD, the Assistant Secretary for Health and Director of the National Vaccine Program, and respond to the following question: *The FDA standards for approval and licensure of vaccines for COVID-19 addresses safety and effectiveness and encourages inclusion of minorities, the elderly, pregnant women, and people with medical comorbidities in clinical trials. In particular, for COVID-19 vaccines, I am interested in the approach the nation should take in regard to vaccination of children, given that there will be relatively little data on children from some of the early clinical trials? As context, the case fatality rate for children under age 18 is .02%. What is the appropriate approach, and timing, of generating the needed data and proceeding to potential childhood vaccination as we move forward?* The NVAC will also review a draft report of the response to the full charge. Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: <http://www.hhs.gov/nvpo/nvac/index.html>.

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit written comments in advance. Written comments should not exceed three pages in length. Individuals submitting comments should e-mail their written

comments or their request to provide a comment during the meeting to *nvac@hhs.gov* at least five business days prior to the meeting.

Dated: October 27, 2020.

Ann Aikin,

Acting Designated Federal Official,

Office of the Assistant Secretary for Health.

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